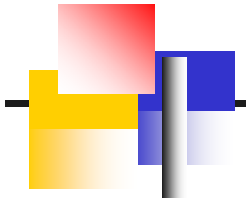
EDAN INSTRUMENTS, INC.

CE 0123



CADENCE II

Fetal Monitor

User Manual

Manual Ver.: 1.4
Release Date: Sep. 2009
Part No.: MS1R-104338-1.4

P/N: MS1R-104338-1.4

Copyright

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) can not be held liable.

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EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠WARNING⚠

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

⚠CAUTION⚠

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE: A NOTE provides useful information regarding a function or a procedure.

Revision History

Date	ECO#	Version	Description
2008/06/27	---	1.0	1st edition
2008/11/30	ECO-QR-8037	1.1	Added information about paper checking and diagnosing principle. Revised battery capacity, compliance standards, ultrasonic& TOCO&IUP specifications in Appendix 1. Corrected terms and grammar.
2009/03/31	ECO-QR-9008	1.2	Added low power summary table. Revised grammar and punctuation.
2009/06/24	ECO-QR-9019	1.3	Revised grammar and punctuation. Added disposing method of waste batteries and explanation of a symbol.
2009/09/10	ECR-CAD-9004	1.4	Added key volume adjustment, warning notes. Revised SOV position, DECG volume and the format of the specification tables.

Table of Contents

Chapter 1 Safety Guidance

NOTES:

1) In order to ensure the operator and patient's safety, read through this chapter before using this monitor.
2) This user manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters and functions described, depending on what you have ordered.

1.1 Intended Use

The CADENCE II fetal monitor is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. It is not intended for use in intensive care units, operating rooms or for home use.

1.2 Instruction for Safe Operation

- The CADENCE II Fetal Monitor (hereinafter called "CADENCE II") is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- CADENCE II operates within specifications at ambient temperatures between 5 ºC (41 ºF) and 40 ºC (104 ºF) after it is powered on for one minute. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least two inches (5 cm) clearance around the instrument for proper air circulation.
- You must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before each use. If damage is evident, replacement is recommended before use.
- The monitor must be serviced only by authorized and qualified personnel. EDAN does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- Perform periodic safety testing to ensure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- The protective categories against electric shock of the patient connections are:

1) Ultrasound (FHR1, FHR2) 2) External TOCO

3) Fetal Movement (FM) 4) Fetal Stimulator (FS)

This symbol indicates that this is an IEC/EN 60601-1 Type B applied part.

 IUP

This symbol indicates that this is an IEC/EN 60601-1 Type BF applied part.

 DECG

This symbol indicates that this is an IEC/EN 60601-1 Type CF applied part.

- The monitor described in this user manual is not protected against:
  a) The effects of defibrillator shocks
  b) The effects of defibrillator discharge
  c) The effects of high frequency currents
  d) The interference of electrosurgery equipment

1.3 Ultrasound Safety Guide

Fetal Use

The CADENCE II Fetal Monitor is designed for continuous fetal heart rate monitoring during pregnancy and labor. Clinical interpretation of fetal heart rate trends can diagnose fetal and/or maternal problems and complications.

Instructions for Use in Minimizing Patient Exposure

The acoustic output of CADENCE II is internally controlled and can not be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure. The exercising of clinical judgment in the monitoring of low risk patients will avoid unnecessary insonation.

1.4 Safety Precautions

To avoid the possibility of injury, observe the following **WARNING** and **CAUTION** messages during the operation of the instrument.

⚠WARNING⚠:

For using safety:

- CADENCE II is provided for the use of qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
- Only qualified service engineers can install this equipment. Only service engineers authorized by EDAN can open the case.
- This device is not intended for home use.
- **EXPLOSION HAZARD** - Do not use the monitor in the presence of flammable anesthetics or other materials.

- **SHOCK HAZARD** - The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.
- Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition.
- Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on the same patient.
- Do not switch on device until all cables have been properly connected and verified.
- Do not touch the signal input or output connector and the patient simultaneously.
- Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.
- Disconnect the power cord before changing fuses. Replace them with those of the same specifications only.
- **SHOCK HAZARD** - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
- **SHOCK HAZARD** - Do not remove the top panel cover during operation or while power is connected.
- The monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.
- To ensure the proper working of the monitor, only connect accessories supplied or recommended by EDAN to the device.
- Accessory equipment connected to the analog and digital interfaces must be validated according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

For proper monitoring:

- This device is not intended for treatment.
- The fetal spiral electrode and intrauterine pressure catheter are disposable. Discard

them after use.

- The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.
- To avoid delay of treatment, alarms must be set according to different conditions of patients. Make sure that audio sounds can be heard when an alarm occurs.

For using the battery:

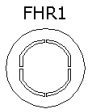
- Read this manual thoroughly before using the battery. Improper operation may cause the battery to get hot, catch fire, explode, be damaged or attenuated in energy.
- Do not heat or throw the battery into fire.
- Do not immerse, throw or wet battery in water/ seawater.
- Do not use, leave the battery close to fire or other places where temperatures may be above 60°C (140 ºF).
- Do not destroy the battery, pierce it with a sharp object, hit it with a hammer or drop it on a hard ground. This may cause battery explosion.
- Do not connect the battery directly to an electric outlet or cigarette lighter charger.
- Do not solder the leading wire and the battery terminal directly.
- Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
- If liquid leaking from the battery splashes into your eyes, do not rub them. Wash them well with clean water and see a doctor immediately.
- If liquid leaks of the battery onto your skin or clothes, wash well with fresh water immediately.
- Use the battery only in CADENCE II.

CAUTION:

- Federal (U.S.) law restricts this device to sale by or on the order of a physician.
- The device is designed for continuous operation and is “ordinary” (i.e. not drip or splash-proof). Keep it far from corrosive medicine, dust area, high-temperature and humid environment.
- Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.
- Sterility can not be guaranteed if the package of the fetal spiral electrode is broken or opened.
- Do not sterilize the monitor or any accessory.
- **Electromagnetic Interference** - Ensure that the environment in which the fetal monitor is installed is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.

- While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
- Do not short-circuit the battery socket or the battery plug.
- If the battery connector becomes dirty, wipe it with a dry cloth.
- The recommended charge temperature range is from 0 ℃ (32 ℉) to 40 ℃ (104 ℉). Do not exceed these ranges.
- Batteries have life cycles. If the time that the monitor uses the battery becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one the same as the one provided or recommended by EDAN.
- When not using battery for an extended period, or any peculiar smell, distortion or discoloration is detected, remove it from the monitor and dispose of it properly.
- The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

1.5 Definitions and Symbols



Socket for ultrasound transducer 1 (Type B applied part)

Socket for TOCO transducer (Type B applied part) or IUP cable (Type BF applied part)

Socket for ultrasound transducer 2 (Type B applied part)

Socket for DECG cable (Type CF applied part)

Socket for Remote Event Marker (Type B applied part)

Socket for Fetal Stimulator (Type B applied part)

Power Socket

Fuse Socket

DB9 interface (for connection to wireless network module)

RJ45 Interface

Equipotential Grounding System

Attention, Consult Accompanying Documents

Type B Applied Part

Type BF Applied Part

Type CF Applied Part

The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.

The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.

The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life and that this unit was put on the market after 13 August 2005.

P/N Part Number

Serial Number

Date Of Manufacture

Manufacturer

Authorized Representative in the European Community

Recycle

Rx only (U.S.) Federal (U.S.) Law restricts this device to sale by or on the order of a physician

Chapter 2 Installation Guidance

NOTE:

Installation must be carried out by qualified personnel authorized by the manufacturer.

2.1 Opening the Package and Checking

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables and accessories.

If there is any problem, contact us or your local distributor immediately.

2.2 Installing Battery

⚠WARNING⚠:

Switch off the monitor and unplug it before installing or removing the battery.

(1) Battery Installation

- Carefully place the monitor upside down on a flat surface covered with cloth or other types of protecting pad.
- Remove the screw of the battery compartment.
- Remove the battery compartment cover.
- Take the battery out from package. Place the battery into the compartment with the wired direction on the outside.
- Insert the cable connector into the socket.
- Close the battery compartment cover and fix it with the screw.

(2) Battery Removal

The steps of battery removal are opposite to those of battery installation.

NOTES:

1) When a battery is configured, after the device is transported or stored, the battery must be charged. Connecting the monitor to AC power supply will charge the battery no matter if the monitor is powered on.
2) If a rechargeable battery is configured, charge it fully each time after use to ensure the electric power is enough.

2.3 Connecting the Power Cable

- Use the power cord provided with the monitor. Put the connector of the power cord into the power socket on the monitor. Put the plug of the power cord into a grounded 3-slot power output special for hospital usage.
- Make sure the AC power supply complies with the following specification: 100V-240V~, 50Hz/60 Hz.

⚠WARNING⚠:

If the protective grounding (protective earth) system is doubtful, the monitor must be powered only by the inner power.

2.4 Feeding Paper

Feeding Paper

If the paper is used up or a paper jam happens, you have to feed paper. The operation procedure is as follows:

1) Press the ⁘ position simultaneously on both sides of the recorder cover to open the paper compartment.
2) Take out the Z-fold thermosensitive paper from the wrapper. Place the pack in the compartment with the pane facing down and the green safety area on the left.
3) Feed the recorder paper into the paper advance slot (Figure 2-1). The paper will come out from the notch automatically. Adjust the paper length by rotating the gear on the left of the handle if required.

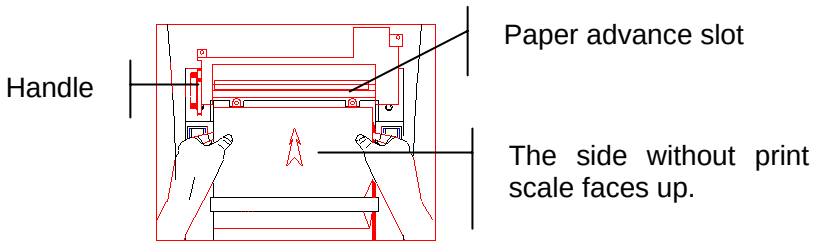


Figure 2-1 Diagram of feeding paper

4) If the paper is slantwise, pull the handle up and rotate the gear to force the paper out. Push the handle down and then feed paper again.
5) After closing the cover, make sure that the paper can come out from the paper notch.

NOTES:

1) When feeding paper, the black handle must be down. If a paper jam happens, pull up the handle first, and then push the gear to force the paper out.
2) Feed the paper gently and avoid touching the print head.

3) Make sure the paper coming out from the notch aligns with the notch edges. Otherwise, the trend printed on the recorder paper will be inaccurate or paper jam may happen.

4) Only use EDAN approved paper to avoid poor printing quality, deflection and paper jam.

5) The printing function cannot be executed when ultrasound transducer or DECG cable connector falls off.

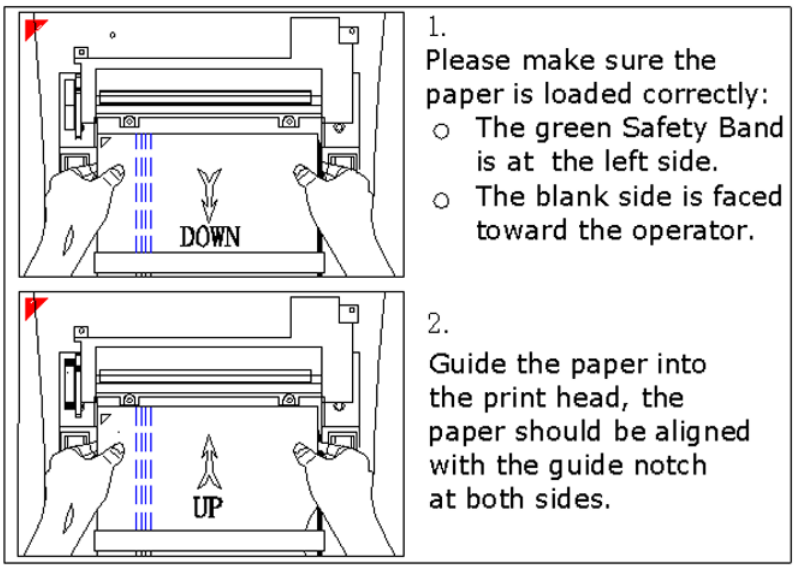


Figure 2-2 Diagram of feeding paper correctly

NOTE:

Be careful when feeding paper. Avoid damaging the thermosensitive print head. Unless feeding paper or shooting troubles, do not leave the recorder compartment open.

Removing Paper Jam

When the recorder does not function or sound properly, open the paper compartment to check for a paper jam. Remove the paper jam in this way:

- Cut the recorder paper from the paper notch edge.
- Open the paper compartment, and then rotate the gear of the recorder.
- Remove the rest of the paper.
- Feed the paper again.

Chapter 3 Introduction

3.1 Functions

The CADENCE II Fetal Monitor can provide different configurations according to different user requirements: FHR1 (Fetal Heart Rate 1), FHR2 (Fetal Heart Rate 2), TOCO, AFM (automatic fetal movement monitoring), MFM (manual fetal movement monitoring), FS (fetal stimulator, optional), DECG (direct fetal ECG, optional) and IUP (Intra-uterine Pressure, optional).

A 5.7" LCD display is applied by the monitor to display the FHR1, FHR2/DECG (dual configuration) and TOCO/IUP trend and numerics. Also a built-in thermal recorder is used to print the trends and other information. A rechargeable lithium-ion battery is provided for your option.

A DB9 interface is built in the monitor. With it, the monitor can be connected to a computer or the MFM-CNS central monitoring system via 485 network. Optionally, you can order a built-in wireless network module to connect the monitor via wireless network. The data collected and stored by CADENCE II can be analyzed by the Insight software running on PC or MFM-CNS (Refer to ***MFM-CNS Central Monitoring System User Manual*** and the relevant information of wireless network module).

3.2 Monitor

NOTE: The pictures and interfaces in this manual are for reference only.

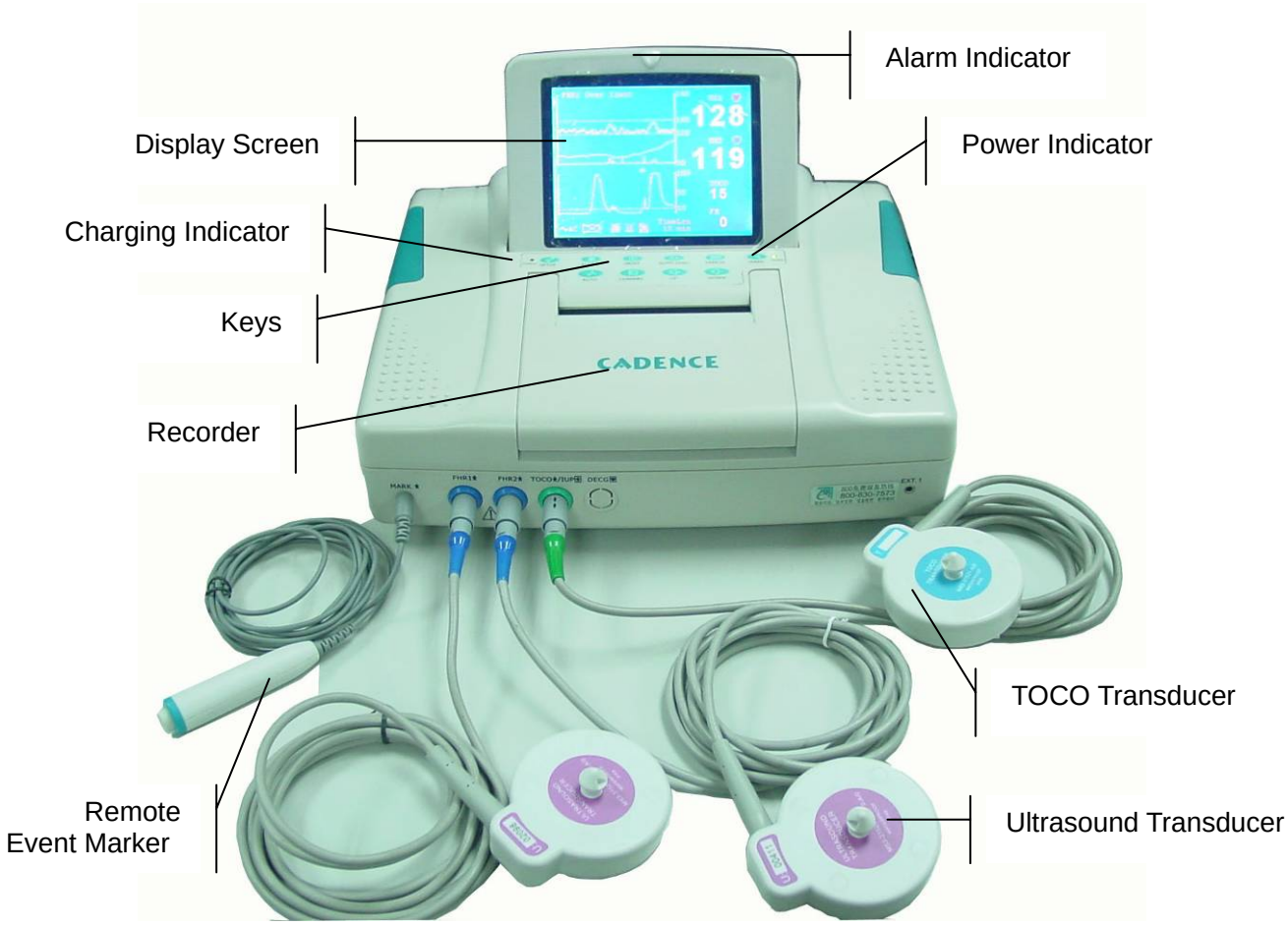


Figure 3-1 CADENCE II appearance (dual configuration)

3.2.1 Display

The display of the monitor is used to show the information of the monitor, menus, and collected fetal parameters and trends etc.

To fit different mounting situations, the display can be tilted to one of the four preset positions.

To tilt the display, you need to lift the display forward to the desired angle.

To fold the display, you need to push the display backward to the desired angle.

Fold the display completely flat when the monitor is mounted on wall.

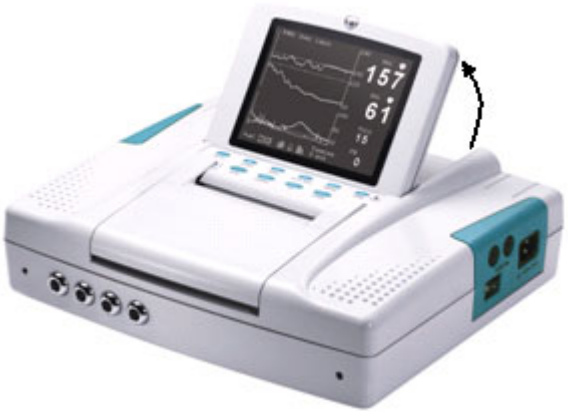


Figure 3-2 To tilt the display

The screen display includes three frames: (1) information frame, (2) trend/menu frame, (3) parameter frame (see Figure 3-3).

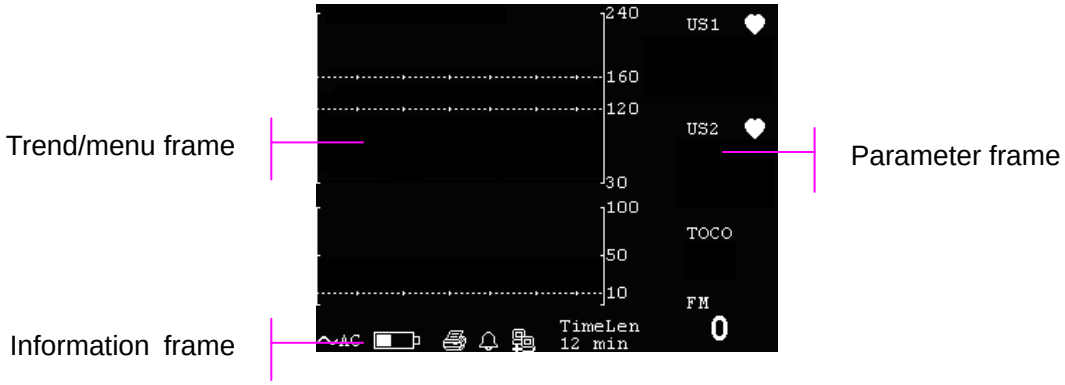


Figure 3-3 Display screen

(1) Information Frame

The information frame is located at the bottom of the screen, which indicates current status of the monitor.

a)  : AC power supplied;

 : no AC power supplied.

b)  : The battery is loaded, and the white pane indicates the charge of the battery;

 means no battery is loaded.

c)  : The recorder is printing;

 : The recorder stops printing.

d)  : The audible alarm sound is activated;

 : The audible alarm sound is inactivated;

e)  : The monitor is online.

 : The monitor is offline.

f) 

: Time length, the duration of the current monitoring.

(2) Trend/Menu Frame

The trend/menu frame occupies most space of the screen. During monitoring and playing back, it displays trends; during setting, it displays setup menus.

i) Main Interface

The background supports two standards: 30 ~ 240 (American standard) and 50 ~ 210 (International standard).

There are two top horizontal graticules within the FHR trend frame. They make it easier for you to estimate if the heart rates have exceeded the preset limits. The FHR1 lower and upper limits determine its range.

The bottom graticule shows the UA baseline.

ii) Setup Menu

The setup menus include: **Function** menu, **Alarm Configuration** menu, **Fetal Monitor Configuration** menu, **Print Configuration** menu, **Interpartum Configuration** menu, **Auto Monitor** menu, **Date and Time** menu and **System** menu.

In the setup menus, the pane that encircles an item is called the cursor. Press the **UP** key or **DOWN** key to move the cursor to the previous or next item. When it comes to the needed item, press the **CHANNEL** key to stop it. This item will be highlighted. This item might have several options, press the **UP** key or **DOWN** key to switch to the previous or next option. When the required option appears, press the **CHANNEL** key to confirm the selection. By then the cursor will turn into the pane and will be able to move among the items again.

If no action is taken in 30 seconds, the system will return to the upper directory.

Press the **SETUP** key again to enter the next setup menu.

Press the **AUTO** key to return to the main interface quickly.

(3) Parameter Frame

Parameter frame lies on the right of the trend frame. The monitoring values are displayed here.

3.2.2 Key Functions and Operations

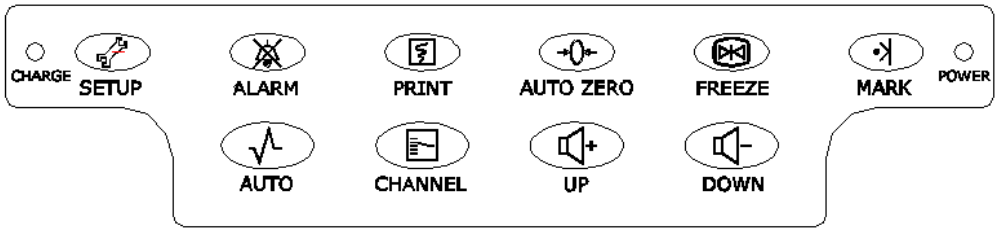


Figure 3-4 Keys

CADENCE II Fetal Monitor is a user-friendly device with operation conducted by a few keys on the monitor. Their functions are as follows:

(1) SETUP key

Function: Enter setup menus.

There are eight setup menus in the monitor. Keep pressing this key, the monitor will switch among the eight setup menus and the main interface in turn.

(2) ALARM key

Function: Disable/Enable the audible alarm.

Press this key, the audible alarm toggles between on and off.

(3) PRINT key

Function: Enable/Disable printing

Press this key to start printing. Press this key again to stop printing.

(4) AUTO ZERO key

Function: TOCO zero

Adjust the external TOCO contractions trend/value to preset unit (external monitoring contractions) or adjust the IUP trend/value to the reference point 0 (internal monitoring contractions).

(5) FREEZE key

Function: Freeze

Freeze the advancing real-time trends and control playback trends.

(6) MARK key

Function: Record an event.

Press this key to make a patient event.

During playback this key is invalid. An abnormal audio will be heard when you press it.

(7) AUTO key

Function: Start monitoring or return to the main interface

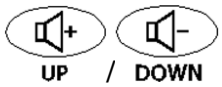
Press this key to start monitoring (on the main interface) or return to main interface (in setup menus).

(8) CHANNEL key

Function:

1) If US1 socket and US2 socket are separately connected with an ultrasound transducer during monitoring, press this key, the fetal heart sound will toggle between US1 and US2. The default fetal heart sound comes from US1.

2) In the setup menus, when the cursor is located at the required item, press this key to confirm selection.



(9) UP / DOWN UP key / DOWN key

Function:

1) During monitoring, press the **UP** key to increase the fetal heart sound volume of the current channel; press the **DOWN** key to decrease the fetal heart sound volume of the current channel.

2) During playback, press the **UP** key to play backward; press the **DOWN** key to play forward;

3) In the setup menus, press the **UP** key to move the cursor downward among the menu items; press the **DOWN** key to move the cursor upward among the menu items.

4) In the setup menus, if an item is highlighted, press the **UP** key to adjust the item value to the previous available option; press the **DOWN** key to adjust the item value to the next available option.

3.2.3 Indicators

Indicator	Status of Indicator	Indication
Alarm Indicator	Light up or flash in orange	An alarm is active.
	Green or off	No alarm is active.
Power Indicator	On	The monitor is powered on.
	Off	The monitor is powered off.
Charging Indicator	On	The battery is being charged.
	Off	No battery or electric charge is full.

Table 3-1 Indicator description

3.2.4 Sockets on the Right Side of the Monitor

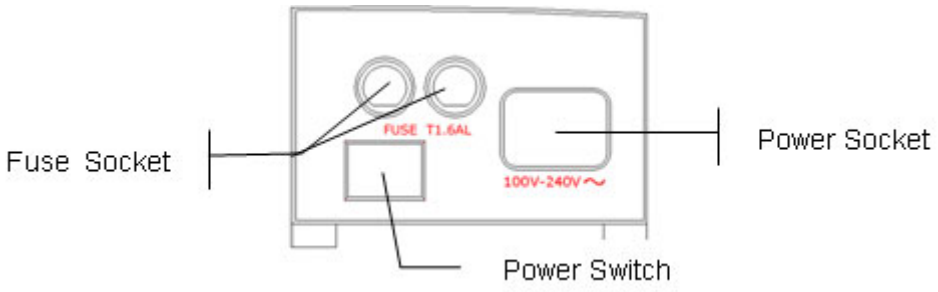


Figure 3-5 Sockets on the right side of the monitor

Power Switch: On/Off switch.

Fuse:

Size: Φ5mm*20mm Model: T1.6AL 250V

Power Socket: Input socket for the mains supply 100V-240V~, 50Hz/60Hz.

3.2.5 Base Panel

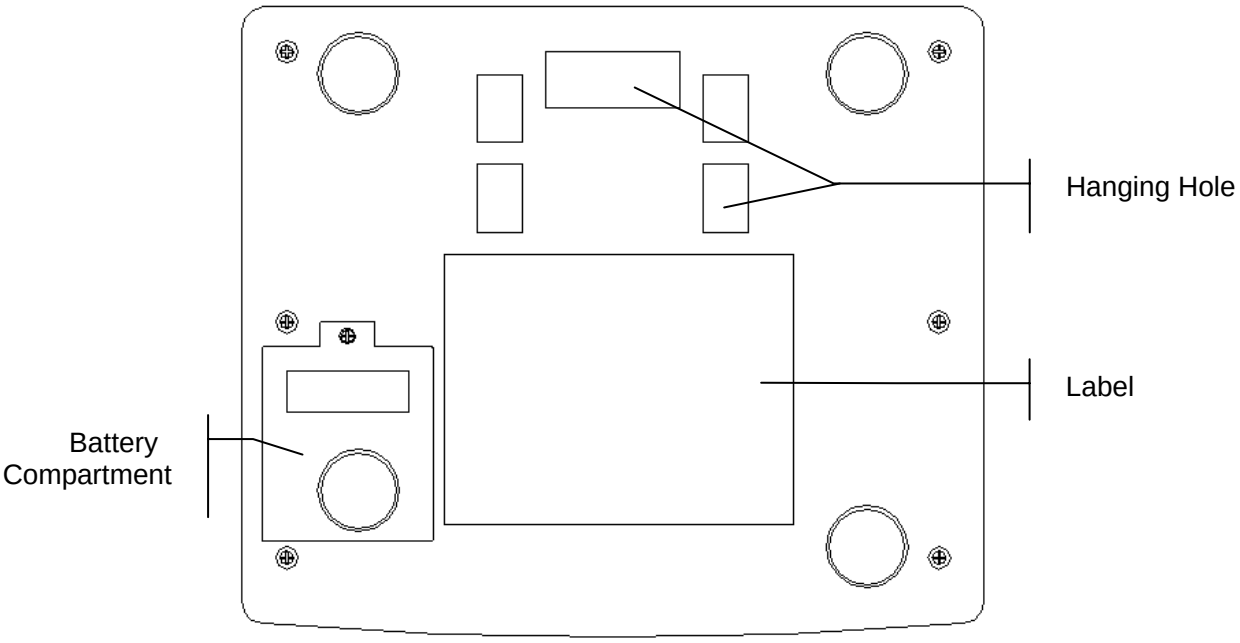


Figure 3-6 Base panel

3.3 Transducers and Cables

The ultrasound transducer(s) and TOCO transducer, IUP cable connector, DECG cable connector, and fetal remote marker are attached to the front panel of the monitor. Each cable has a tab located on the connector housing to ensure proper insertion into the appropriate socket on the monitor.

3.3.1 Transducers

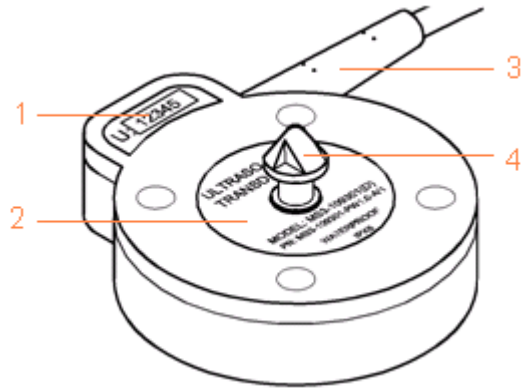


Figure 3-7 Ultrasound (US) transducer

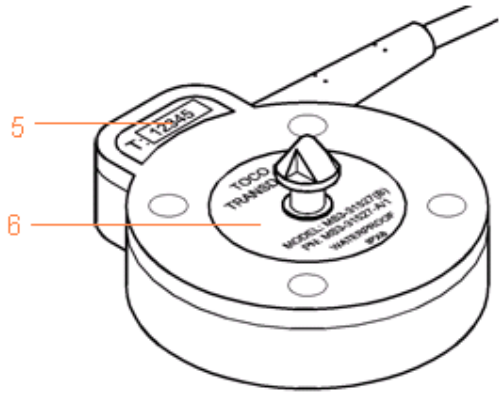


Figure 3-8 TOCO transducer

1 Serial number label of the US transducer, pink. U:xxxxx is the serial number.
2 Specification label of the US transducer, pink.
3 Transducer cable
4 Belt buckle
5 Serial number label of the TOCO transducer, blue. T:xxxxx is the serial number.
6 Specification label of the TOCO transducer, blue.

Information on the specification label includes:

PN: MS3-109301: Part number of this US transducer.

MS3-31527: Part number of this TOCO transducer.

PW 1.0: pulsed wave, the central frequency of the US transducer is 1.0 MHz.

A/1: Version number of the transducer.

WATERPROOF: means the transducer is waterproof.

IPX8: means the transducer can work continuously for 5 hours under 1-metre water without being waterlogged.

CAUTION:

The waterproof parts of the US/TOCO transducer are restricted to the main body and the cable. Do not immerse the plug into any liquid in the process of monitoring or cleaning.

3.3.2 Remote Event Marker

The remote event marker is a hand-held switch operated by patient. The mother is normally instructed to push down this switch when feeling a fetal movement.

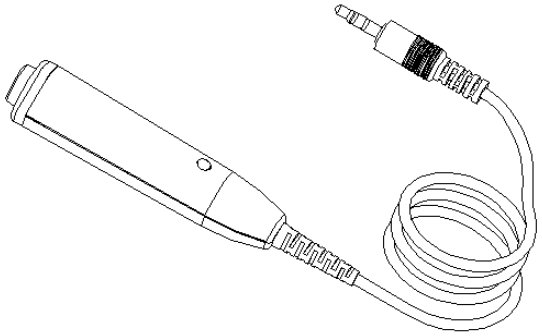


Figure 3-9 Remote event marker

3.3.3 Fetal Spiral Electrode

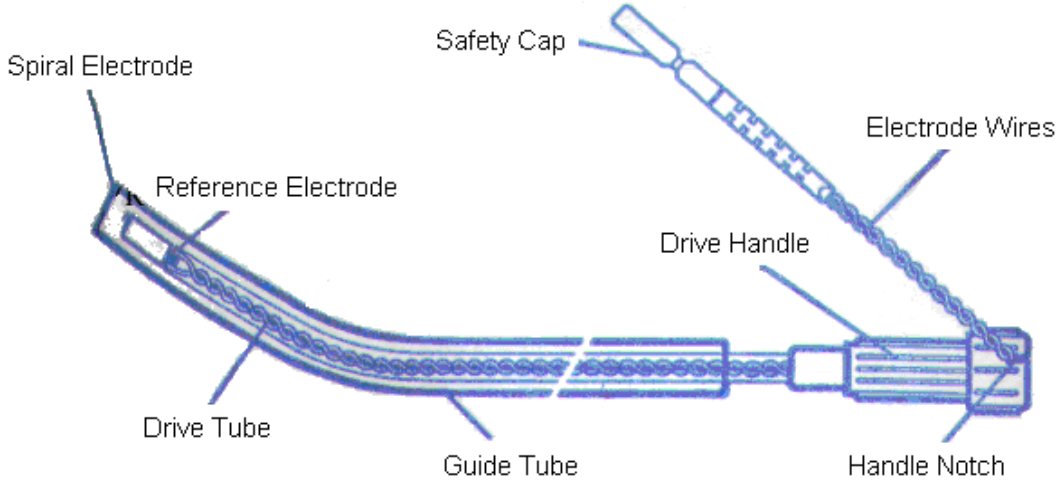


Figure 3-10 Spiral electrode

3.4 Ordering Information

Accessories supplied or approved by EDAN can be used with the monitor. See the following table for details. The accessories employed by EDAN, such as the rechargeable battery (model No.: HYLB) manufactured by HENGYU are products having passed the authentication of CE, and they have the characteristics specified by their manufacturers.

Accessory	**Part Number**
Ultrasound Transducer	MS3-109301
TOCO Transducer	MS3-31527
Remote Event Marker	MS3-107673
Belt	MS2-02264

Coupling Gel (0.25ltr bottle)	M50-78001
Fetal Stimulator	MS9-17660
DECG Cable	MS2-12148
Disposable Fetal Spiral Electrode	MS0-02145
Disposable Maternal Attachment Pad Electrode	MS0-02146
Intrauterine Pressure Cable Connecting Wire	MS1R-107796
Intrauterine Pressure Cable	MS1-104152
Disposable Intrauterine Pressure Catheter	MS1-104153
Rechargeable Lithium-ion Battery	M21-064117
Thermosensitive Paper (American Standard)	MS1-01921
Thermosensitive Paper (European Standard)	M50R-78019
Fuse T1.6AL 250V	M21-64010
Power Cord (American Standard)	M13-36015
Power Cord (European Standard)	M13R-36014
Rechargeable lithium battery	M21-064117

Chapter 4 Alarm

4.1 Alarms Classification

When a patient's vital sign exceeds its configured limit, or the monitor can not measure and therefore can not detect critical patient conditions reliably, the monitor initiates alarm signals to attract the physician's attention.

In terms of severity, the alarms are divided into two levels: medium and low. Medium level alarm is a severe warning; low level alarm is a general warning.

The medium level alarms have higher priority than the low level alarms. If both types of alarms are active at the same time, the monitor sounds an audible indicator for the medium level alarms.

4.2 Audible Alarm

When an alarm is active, the monitor gives out an alarm sound.

Medium level alarm: a "Do" tone is repeated three times, followed by a pause.

Low level alarm: a "Do" tone is issued, followed by a pause.

Press the **ALARM** key on the front panel, the audible alarm will toggle between on and off. Meanwhile, the audible alarm indicator on the main interface toggles between  and  . However, the alarm messages will still be displayed and the alarm indicator will still be lit up when an alarm is active.

⚠WARNING⚠:

Do not disable the audible alarm for the condition where the patient's safety may be endangered.

4.3 Visual Alarm

When an alarm is active,

- the alarm indicator flashes in orange with a frequency of 0.5Hz if it is a medium level alarm; the alarm indicator lights up in orange if it is a low level alarm.

- the alarm message appears at the top left corner of the monitoring screen.

When more than one alarm is active, the alarm messages appear in the same area in succession.

NOTE:

The alarm message can never be cancelled unless the alarm is switched off.

4.4 Treatment Measures

When the monitor gives out an alarm and catches your attention, you should:

- Check the patient's condition;

- Identify the cause of the alarm;

- Silence the alarm if necessary;

Check if the alarm is terminated when the alarm condition is solved.

4.5 Testing Alarms

To test the functions of visible and audible alarms, do the following:

1 Switch on the monitor.

2 Enable the alarm.

3 Set the alarm limits to a small range.

4 Stimulate a signal that is higher than the upper limit or lower than the lower limit. Or disconnect one of the plugs.

5 Verify if the visible and audible alarms are working properly.

4.6 Alarm Messages

The table below lists the alarm information that might appear during fetal monitoring, and their respective causes and countermeasures.

Alarm Message	Cause	Countermeasure
Medium Level Alarm		
FHR1 Over limit	The FHR1 measurement result is higher than the preset upper limit or is lower than the preset lower limit over the alarm keep time.	Check if the alarm limits are suitable; check the woman's condition.
FHR2 Over limit	The FHR2 measurement result is higher than the preset upper limit or is lower than the preset lower limit over the alarm keep time.	
DECG Over limit	The DECG measurement result is higher than the preset upper limit or is lower than the preset lower limit over the alarm delay time.	

Low Level Alarm		
FM Board fault	The fetal monitoring board can not communicate with the system successfully.	Restart the monitor and try again, contact EDAN if the connection still fails.
DECG Board fault	The DECG board can not communicate with the system successfully.	Restart the monitor and try again, contact EDAN if the connection still fails.
US1 probe off	Ultrasound transducer 1 is not well connected.	Check the connection of the transducer.
US2 probe off	Ultrasound transducer 2 is not well connected.	
TOCO probe off	TOCO transducer is not well connected.	
DECG probe off	The DECG lead is not well connected to the monitor.	Check the connection of the DECG cable.
IUP probe off	The IUP connecting cable is not well connected to the monitor.	Check the connection of the IUP connecting cable.
US1 quality bad	FHR1 signal is too weak for the system to process analysis.	Check if the US transducer 1 is well aimed at the fetus; check the woman's condition.
US2 quality bad	FHR2 signal is too weak for the system to process analysis.	Check if the US transducer 2 is well aimed at the fetus; check the woman's condition.
DECG quality bad	DECG signal is too weak for the system to process analysis.	Check if the spiral electrode is well attached to the fetus; check the woman's condition.
DECG lead off	The spiral electrode is not well connected.	Check the connection of the spiral electrode.
Low battery energy	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
Signals Overlap	The two US transducers are aimed at the same fetal heart, or the US transducer is aimed at the fetus that the fetal spiral electrode is attached to.	Adjust one of the US transducers until another fetal heart signal is detected.

4.7 Alarm Defaults

Alarm Setting	Options	Default
FHR1/FHR2/DECG Alert	On, Off	On
FHR1/FHR2/DECG Lower Limit	50 bpm ~ 130 bpm, in increments of 5.	120 bpm
FHR1/FHR2/DECG Upper Limit	150 bpm ~ 210 bpm, in increments of 5.	160 bpm
FHR1/FHR2/DECG Keep Time	0 ~ 30 second(s), in increments of 5.	30 seconds
US1/US2/DECG Probe Detecting	On, Off	On
FHR1/FHR2/DECG Signal Quality Detecting	On, Off	On
UA Probe Detecting (Toco transducer detecting)	On, Off	On
SOV (signals overlap verification)	On, Off	Off

Chapter 5 Printing

5.1 Function Description

The built-in thermal recorder applied in CADENCE II prints continuous FHR1/ FHR2 (DECG) /TOCO /AFM trends synchronously along with some other symbols:

- A list of date, time, TOCO type, print speed, BedID and FHR2/DECG offset (at the beginning of the printing).
- The current time (every 10 minutes afterward).
- Trends marks (FHR1, TOCO ext/TOCO int, AFM) (every 8 minutes afterward).
- Symbol marks (Start, Alarm, FM, event, zeroing) (whenever it happens).

The monitor supports some other functions listed below:

- **Auto Start Printing:** If this function is enabled, the recorder starts printing automatically when a new monitoring starts (the **AUTO** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Fixed Length Printing:** The recorder prints trends of a fixed time length each time. A music sound will be heard at the end of the printing. This length is adjustable. Refer to *5.2.3 Choosing the Printing Time Length.*
- **Data Caching:** When the paper drawer runs out of paper, the recorder stops printing. The data from this moment on (at most 15 minutes) will be temporarily saved in the internal memory. When new paper is loaded, the recorder resumes printing automatically.

  NOTE:

  If both the US transducer and the DECG cable are unplugged, or if the monitor is switched off, the data in the internal memory will be lost.
- **FHR2 Offset:** You can set the offset of the FHR2 trend to separate the two FH trends on the screen and the recorder paper. Refer to *7.4.4 Changing FHR2/DECG Offset*.
- **Print Test:** The recorder prints a trend for self-testing when the monitor is switched on.

The following factors may cause the printing failure:

- Pressing the **PRINT** key frequently. (You should allow the recorder to print the last row before pressing the key again to start another printing.)
- Neither ultrasound transducer nor DECG cable is connected to the monitor.
- The recorder runs out of paper.
- Recorder failure.

5.2 Printing Configuration

CAUTION:

Set the recorder well before printing starts. You can not change its configuration in the process of printing.

5.2.1 Switching Auto-Print On and Off

1 Press the **SETUP** key six times to open the **Auto Monitor** menu.
2 Press the **CHANNEL** key when the cursor stays at **Print**.
3 Press the **UP** key or **DOWN** key to toggle between **ON** and **OFF** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

5.2.2 Choosing the Paper Speed

1 Press the **SETUP** key four times to open the **Print Configuration** menu.
2 Press the **CHANNEL** key when the cursor stays at **PSpeed**.
3 Press the **UP** key or **DOWN** key to choose the paper speed from 1cm/min, 2cm/min (default) and 3cm/min.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

5.2.3 Choosing the Time Length

1 Press the **SETUP** key four times to open the **Print Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Print TimeLen**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the print time length from 0 ~ 250 minute(s). The default is 0. 0 means there is no time limit, the recorder will not stop until the **PRINT** key is pressed.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

5.2.4 Switching Print Test On and Off

1 Press the **SETUP** key four times to open the **Print Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **PrintTest**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **ON** and **OFF** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

5.3 Examples of Printing Pattern

CAUTION:

1) If there is any difference between the display and the printout, take the printout as criterion.

2) If the data is doubtful, clinicians should use other methods to verify the results or make diagnoses based on the real condition.

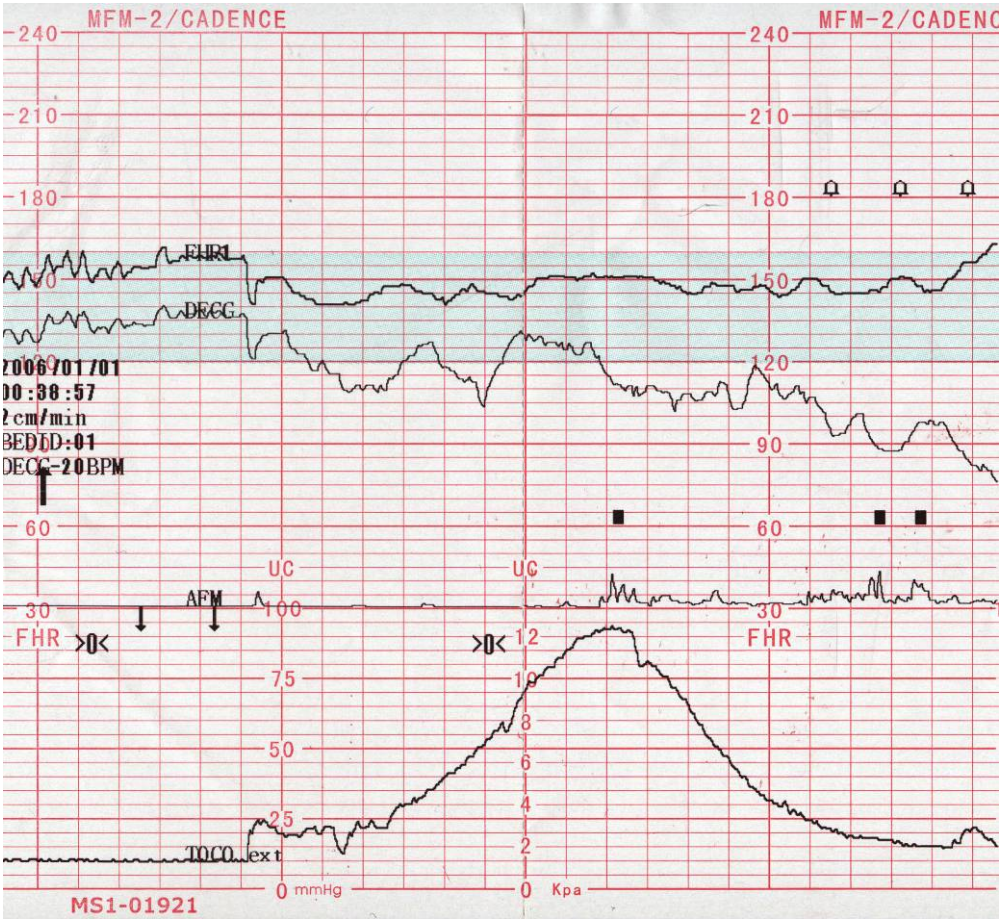


Figure 5-1 An example of printing pattern (American standard recorder paper)

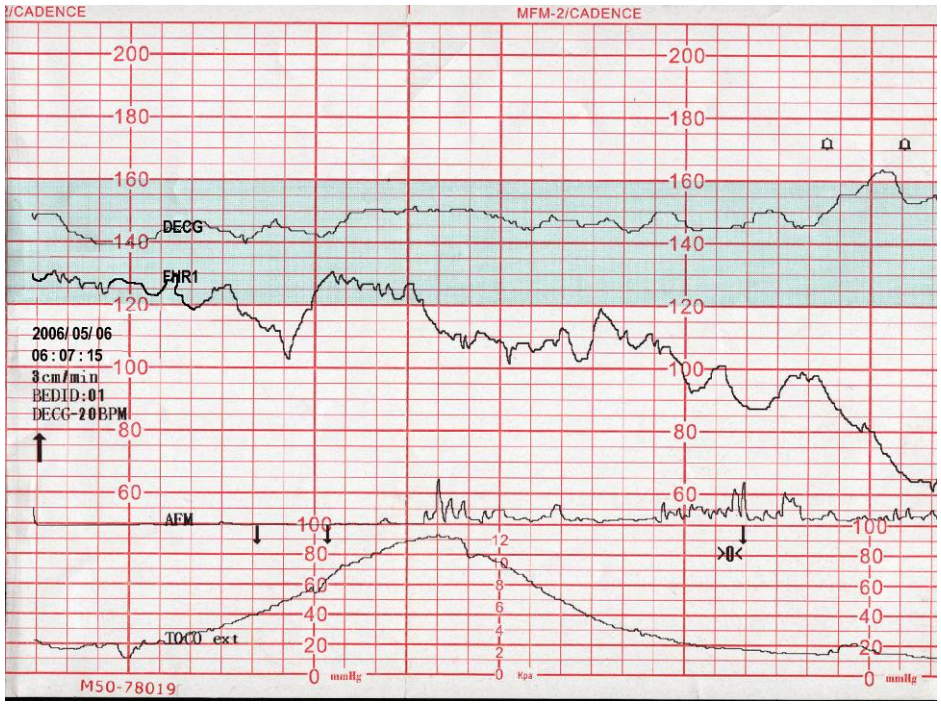


Figure 5-2 An example of printing pattern (international standard recorder paper)

Besides the trends, some other symbols appear among the trends on the recorder paper:

	This symbol indicates that an alarm is active.
	This symbol indicates a manual fetal movement, and it appears after the patient presses the remote event marker when she feels a fetal movement.
	This symbol indicates a fetal movement is detected by the monitor automatically.
	This symbol indicates that the **MARK** key is pressed to record an event, such as the patient turning around, taking injection.
	This symbol indicates that the monitor is zeroed by pressing the **AUTO ZERO** key.
FHR1	FHR1 trend mark. The broad trend is FHR1 trend.
FHR2/ DECG	The narrow trend is FHR2 / DECG trend.
TOCO ext/ TOCO int	The TOCO trend from external / internal monitoring.

Chapter 6 Pre-Monitoring Preparation

6.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG can not differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. These are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.
- Maternal aorta or other large vessels signals.
- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.
- Movement of the deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the fetal monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography.

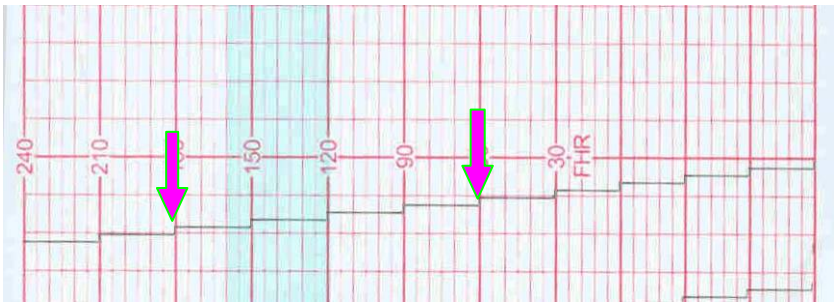
6.2 Switching On the Monitor

⚠WARNING⚠:

1) Check if all the metal parts are linked to the protective earth cord and the cord is working well before powering on the monitor.
2) If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.

Press the **POWER** switch on the right panel to switch on the monitor. The power indicator lights up and a switching-on sound is heard. You can operate the monitor after the main interface appears.

The recorder prints a baseline after the monitor is switched on. Observe the turning points of the printed baselines, they should be printed exactly on the thick scale lines if the recorder paper is correctly loaded and set.



If they do not comply with the lines, reload paper or ask the service engineer to check the paper settings of the monitor.

⚠CAUTION⚠: Make sure the paper is correctly loaded before starting printing.

6.3 Setting Date and Time

1 Press the **SETUP** key seven times to open the **Date and Time** menu.

2 Press the **CHANNEL** key when the cursor stays at **Year**.

3 Press the **UP** key or **DOWN** key to choose the year.

4 Press the **CHANNEL** key to confirm selection.

5 In the same way, choose the month from 1 ~ 12, the day from 1 ~ 31 (depending on the year and month), the hour (in 24 hour format) from 0 ~ 23, the minute from 0 ~ 59 and the second from 0 ~ 59.

6 Press the **AUTO** key to exit.

NOTE:

The date and time remain in the monitor for at least two months after it switches off. You do not have to set date and time before monitoring each time.

6.4 Connecting Transducers

Check for visible damages of the transducers before connecting them to the monitor every time. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them with good ones at once.

When plugging transducers into the sockets, make sure the arrow symbol of the connector is facing up, refer to figure 6-1.

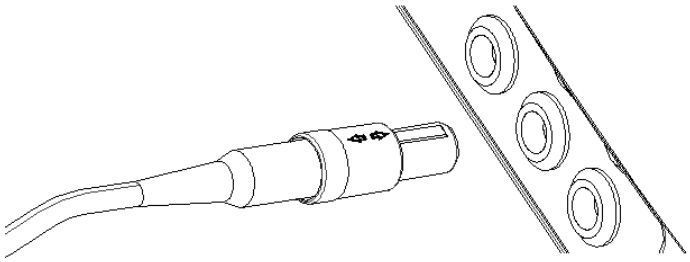


Figure 6-1 Connecting the transducer

When disconnecting a transducer, hold the afterbody of the transducer outshell (the shaded part shown in figure 6-2) with fingers and push it in slightly, and then pull it out. Refer to figure 6-2.

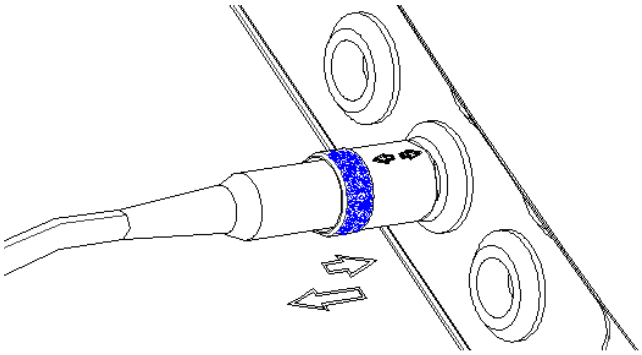


Figure 6-2 Disconnecting the transducer

6.5 Adjusting the Volume

The monitor automatically detects which channel the ultrasound transducer is connected to. If both channels are connected with US transducers, the fetal heart sound of US1 is heard by default. You can press the **CHANNEL** key to switch the sound to US2.

Adjust the default monitoring volume:

The fetal heart sound volume returns to a default level in new monitoring after the **AUTO** key is pressed. This default level is adjustable. To change this level,

1 Press the **SETUP** key six times to open the **Auto Monitor** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Volume**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the volume from 0 ~ 9; the default is 3.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

Adjust the real-time monitoring volume:

If the default volume is not satisfactory during monitoring, you can press the **UP** key or **DOWN** key to increase or decrease the volume of the current channel. Press the **CHANNEL** key and adjust the volume of the other channel in the same way.

Adjust the key volume:

When a key is pressed, the monitor gives a “Di” sound. This volume is also adjustable.

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Key Volume**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the key volume from **High**, **Low** (default) and **Off**.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

NOTE:

When the monitor does not execute the function of a key, it gives a “Do” sound.

Chapter 7 Monitoring

⚠WARNING⚠:

1) The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.
2) The monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.
3) Always check if the alarm settings are appropriate for your patient before starting monitoring.

7.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG can not differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. These are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.
- Maternal aorta or other large vessels signals.
- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.
- Movement of the deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the fetal monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography.

7.2 Monitoring FHR with Ultrasound

The ultrasound monitoring is a method to obtain FHR through maternal abdominal wall. Place a US transducer (US transducer) on maternal abdomen to transmit lower energy ultrasound wave to fetal heart, and then receive the echo signal.

Ultrasound monitoring can be used for antepartum monitoring.

7.2.1 Parts Required

1) US transducer 2) Aquasonic coupling gel 3) Belt

7.2.2 Operation Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen

when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Acquiring FH Signal

Search for the location of the fetal heart using a stethoscope or a fetoscope.

Apply a certain amount of acoustic gel on the transducer and move it slowly around the fetus site until a clear characteristic hoof-beat sound of the fetal heart is heard. Refer to figure 7-1 for the transducer position.

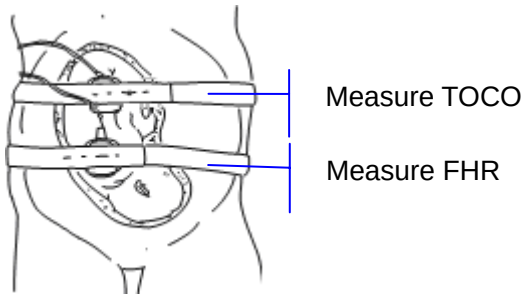


Figure 7-1 Ultrasound transducer & TOCO transducer positioning (single fetus)

3) Fixing the Transducer

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt.

Make sure the belt fits the patient snugly but comfortably. Meanwhile, fetus heart sound is heard clearly and the FHR trace and value are displayed on the screen.

CAUTION:

Do not mistake the higher maternal heart rate for fetal heart rate.

NOTES:

1) The best quality records will only be obtained if the transducer is placed in the optimum position.
2) Positions with strong placental sounds or umbilical blood flow sound should be avoided.
3) If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During examining, the pregnant woman's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.
4) It is impossible to examine FHR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

7.2.3 Switching the FHR Alarm On or Off

Always check if the alarm settings are appropriate for your patient before starting a monitoring.

If the fetal heart alarm is switched off, the monitor no longer gives any audible or visual warning for this monitoring item.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Enabled** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** (default) and **Off**.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

⚠WARNING⚠:

Do not switch off the FHR alarm for the condition where the patient's safety may be endangered.

7.2.4 Changing the FHR Alarm Limits

The alarm limits you set determine the conditions that trigger the alarm.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Lower** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the lower limit from 50 ~130 bpm.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **UP** key or **DOWN** key to move the cursor to **Upper** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
6 Press the **UP** key or **DOWN** key to choose the upper limit from 150 ~ 210 bpm.
7 Press the **CHANNEL** key to confirm selection.
8 Press the **AUTO** key to exit.

7.2.5 Changing the FHR Alarm Keep Time

The alarm keep time indicates how long the measurement result continues exceeding its limit before the alarm is triggered.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Keep** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
6 Press the **UP** key or **DOWN** key to choose the keep time from 0 ~ 30 second(s).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.2.6 Switching the Probe Detecting Alarm On or Off

The monitor detects if the US transducer is well connected. When the transducer is unplugged, the monitor gives an alarm. You can switch this alarm on or off.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Probe** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** and **Off** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.2.7 Switching the FHR Signal Quality Alarm On or Off

When the FHR signal from the US transducer is too weak for the system to process analysis, the monitor gives an alarm. You can switch this alarm on or off.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **Quality** (FHR1 Alert or FHR2 Alert); press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** and **Off** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.3 Monitoring FHR with DECG (optional)

7.3.1 Contraindications

The fetal spiral electrode can be used when amniotic membranes are adequately ruptured and sufficient cervical dilatation is ensured. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique.

The fetal spiral electrode should not be applied to the fetal face, fontanels or genitalia.

Do not apply the fetal spiral electrode when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. This method is not recommended when fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhea, unless a clear benefit to the fetus or mother can be established.

7.3.2 Parts Required

1) DECG cable 2) Disposable fetal spiral electrode 3) Disposable maternal attachment pad electrode

7.3.3 Preparing the Patient's Skin Prior to Placing Electrodes

The skin is a poor conductor of electricity. Therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

7.3.4 Directions for Use of Fetal Spiral Electrode

1) Remove the fetal spiral electrode from package, leaving the electrode wires locked in the handle notch.
2) Gently bend the guide tube to the desired angle.
3) With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.
4) Holding the drive handle, ensure the spiral electrode is retracted approximately one inch (2.5 cm) from the distal end of the guide tube.
5) Place the guide tube firmly against the identified presenting part.
6) Maintain pressure against the fetal presenting part with guide and drive tubes. Turn the drive tube by rotating the drive handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the drive handle indicates attachment. This will usually occur after one complete rotation.
7) Release the electrode wires from the handle notch and straighten them. Slide the drive and guide tubes off the electrode wires.
8) Insert the safety cap into DECG cable.

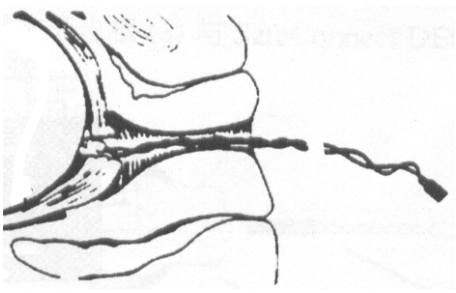


Figure 7-2 Connection for fetal spiral electrode

7.3.5 DECG Monitoring Procedure

1 Perform a vaginal examination to identify the fetal presenting part.

2 Prepare the patient's skin using the procedures described in section *7.3.3 Preparing the Patient's Skin Prior to Placing Electrodes*.

3 Attach the fetal spiral electrode to the fetal presenting part using the procedures described in section *7.3.4 Directions for Use of Fetal Spiral Electrode*.

4 Fix an attachment pad electrode to DECG cable.

5 Remove the film on the back of the electrode and place the electrode on maternal thigh; press it firmly in place.

6 Connect the fetal spiral electrode to the DECG cable.

7 Insert connector of DECG cable into the DECG socket of the monitor.

8 Check the setup of DECG arrhythmia logic.

⚠WARNING⚠:

Do not plug the fetal spiral electrode wire into the power socket.

CAUTION:

Do not mistake the higher maternal heart rate for DECG.

NOTES:

1) If there is any doubt as to the presence of a fetal heart signal with ECG, check with the US transducer on the patient's abdomen or with a separate diagnostic instrument. The presence of an audible Doppler heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.

2) After the electrode is well attached, allow a few minutes for the electrode and fetal tissue to become stabilized. It is essential that the ECG signal electrode is in good contact with the fetal presenting part.

7.3.6 Detaching the Fetal Spiral Electrode

To detach the fetal spiral electrode, rotate it counterclockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin.

Dispose of the used fetal spiral electrode in a proper way. Do not use it again.

7.3.7 Switching DECG Arrhythmia Logic On or Off

When the DECG arrhythmia logic is enabled, the monitor only records the transient heart rate change that is smaller than ±25bpm. If the heart rate change exceeds this limit, it will not be

recorded.

When the DECG arrhythmia logic is disabled, the monitor records all the fetal heart beats.

If you have doubts about arrhythmia of the fetus, disable the DECG arrhythmia logic.

To switch DECG arrhythmia logic on or off,

1 Press the **SETUP** key five times to open the **Interpartum Configuration** menu.
2 Press the **CHANNEL** key when the cursor stays at **DECGAntiArt**.
3 Press the **UP** key or **DOWN** key to toggle between **On** (default) and **Off**.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.3.8 Changing DECG Volume

The monitor also gives a fetal heart sound when monitoring fetal heart rate with DECG. To change DECG volume,

1 Press the **SETUP** key five times to open the **Interpartum Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **DECGVolume**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** and **Off** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.4 Dual Heart Rate Monitoring

7.4.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to FHR1 socket and the second US transducer to FHR2 socket. Follow the instructions described in section *7.2 Monitoring FHR with Ultrasound* to acquire FHR signals for both channels.

When two US transducers are fixed, make sure fetal heart sound from both channels is clear, and two FHR trends / values are displayed on the screen.

7.4.2 Monitoring Internally (Optional)

Alternatively, you can monitor a fetal heart using ultrasound externally, and monitor the second fetal heart using DECG internally.

Connect US transducer to FHR1 socket; connect DECG cable to DECG socket.

Monitor one twin with US transducer using procedures described in section *7.2 Monitoring FHR with Ultrasound*.

Monitor the second twin with DECG cable using procedures described in section *7.3 Monitoring*

FHR with DECG.

NOTE:

If the DECG sound is not switched off, the fetal heart sound of the twins will be heard simultaneously.

7.4.3 Signals Overlap Verification (SOV)

If the two US transducers are aimed at the same fetal heart, or the US transducer is aimed at the fetus that the fetal spiral electrode is attached to, an alarm message "Signals Overlap" will appear on the screen to warn you.

If you are monitoring FHR externally, adjust one of the transducers' position to find the second fetal heart.

If you are monitoring FHR internally, adjust the US transducer's position to find the second fetal heart.

To switch the SOV alarm on or off,

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **SOV**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** and **Off** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.4.4 Changing FHR2/DECG Offset

In order to distinguish FHR1 trend from FHR2/DECG trend, FHR2 offset is provided to help you separate the two trends by an offset of -20 bpm or +20 bpm.

1 Press the **SETUP** key four times to open the **Print Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **FHR2Offset**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the offset from **-20 bpm**, **0 bpm** and **+20 bpm**.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

This preset FHR2 offset will be printed on the recorder paper.

"FHR2 -20bpm" means the FHR2/DECG trend is 20bpm lower than it really is.

"FHR2 0bpm"means the FHR2/DECG trend is staying at where it really is.

"FHR2 +20bpm"means the FHR2/DECG trend is 20bpm higher than it really is.

7.5 Monitoring Uterine Activity (UA) Externally

7.5.1 Parts Required

1) TOCO transducer 2) Belt

7.5.2 Operation Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Fixing the Transducer

Refer to figure 7-1 for the TOCO transducer position. Wipe off any gel remaining on abdomen around this area.

Place the transducer on the patient's fundus to get optimum recording of uterine activity.

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt fits the patient snugly but comfortably.

3) Adjust the Value to Zero

Press the **AUTO ZERO** key to adjust the value to the baseline. Make sure this is not done during a contraction.

The uterine activity reading at this point should be 30 ~ 90. If the numeric exceeds this range, it indicates the belt is too tight or too loose. The too tight belt may cause a flat-top aligned with 100 on the TOCO scale, and the transducer would slide if the belt is too loose. You need to adjust it.

NOTES:

1) Do not apply aquasonic coupling gel on a TOCO transducer or its contact area.
2) Check the function of the TOCO transducer by applying pressure on it to see if this is displayed on the screen.

7.5.3 Changing the UA Baseline

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **UABaseline**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to choose the baseline from 5, 10 (default), 15 and 20.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.5.4 Switching the UA Probe Detecting Alarm On or Off

The monitor detects if the TOCO transducer is well connected. When the transducer is unplugged, the monitor gives an alarm. You can switch this alarm on or off.

1 Press the **SETUP** key twice to open the **Alarm Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **UAProbe**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **On** and **Off** (default).
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.6 Monitoring Uterine Activity Internally (optional)

7.6.1 Parts Required

1) Disposable intrauterine pressure catheter ACCU-TRACE™ IUPC ("IUPC" for short)
2) Reusable intrauterine pressure connecting cable ("connecting cable" for short)
3) Reusable intrauterine pressure cable ("IUP cable" for short)

7.6.2 Directions for Use of IUPC

Preparation

1) Gather supplies: ACCU-TRACE IUPC, reusable cable, and amnioinfusion supplies if needed.
2) Open the sterile ACCU-TRACE IUPC package.

Insertion

NOTE: This product is designed for use with the introducer.

3) Using aseptic technique, remove the catheter from the package.
4) Perform vaginal exam to ensure ruptured membranes and adequate dilation.
5) Advance the catheter tip to the cervical os along the examination hand, using the hand as a guide. Do not advance the introducer through the cervix.
6) Continue to gently advance the catheter tip through the cervical os and feed the catheter into the intra-amniotic cavity until the 45cm mark is at the introitus. If the 45cm mark is not clearly visible, stop advancing when the ● symbol on the catheter meets the introducer.

NOTE: For easier insertion, do not twist the catheter in the introducer.

7) The IUPC may spontaneously fill with amniotic fluid. This can be seen in the clear lumen of the catheter. The filter cap will prevent the amniotic fluid from leaking.
8) Slide the introducer out of the vagina along the catheter. When the introducer is completely out of the vagina, slide thumb between catheter and introducer tab, which will begin to separate the introducer from the catheter. (See figure 7-3)

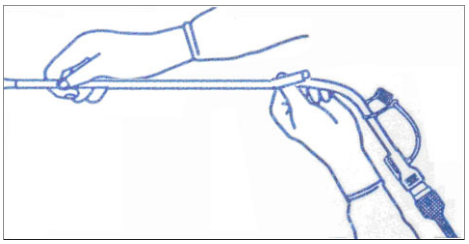


Figure 7-3 Separate the introducer

9) Anchoring the catheter in place with one hand, pull the introducer straight back off the catheter. (See figure 7-4)

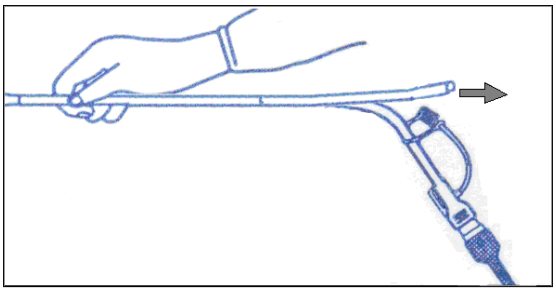


Figure 7-4 Remove the introducer

10) Remove the liner from the adhesive pad, and then adhere the pad to the patient's skin. Secure the catheter by placing the catheter attachment strap to the adhesive pad. (See Figure 7-5).

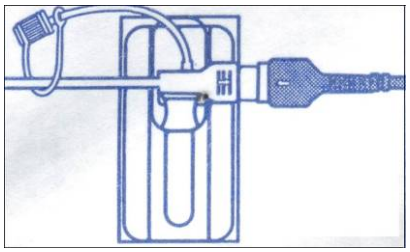


Figure 7-5 Secure the adhesive pad to mother

Rezeroing the System During Monitoring

1) With the catheter connected to the IUP cable, momentarily pressing the re-zero button on the pressure cable (See Figure 7-6). The green light on the cable will flash for five seconds.

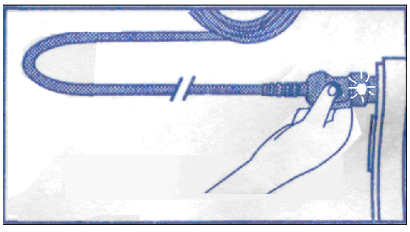


Figure 7-6 Rezeroing the system

2) During this period, adjust the monitor to zero by pressing the **AUTO ZERO** key.

⚠WARNING⚠:

1) Before insertion, placental position should be confirmed, amniotic membranes

adequately ruptured and sufficient cervical dilatation assured.

2) Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use it with caution when uterine infection is present.

3) If resistance is met at any time during insertion, withdraw the catheter slightly and try at a different angle. Forced insertion may result in patient's discomfort or injury.

CAUTION:

1) Since procedures vary according to hospital needs/ preferences, it is the responsibility of the hospital staff to determine exact policies and procedures for both monitoring and amnioinfusion. The safe and effective use of the IUPC depends on the skill of the clinician who applies / uses it.

2) Read *Directions For Use of Disposable IUPC* prior to insertion. The Product has been sterilized by gamma radiation and is sterilized and non-pyrogenic unless package is broken or open. Do not re-sterilize it.

NOTE:

Refer to the instruction on the package for more information about using the IUPC.

7.6.3 Operation Procedure

1) Insert IUPC using the procedure described in section *7.6.2 Directions for Use of IUPC*.
2) Connect the IUP cable to the IUP cable. (See figure 7-7)

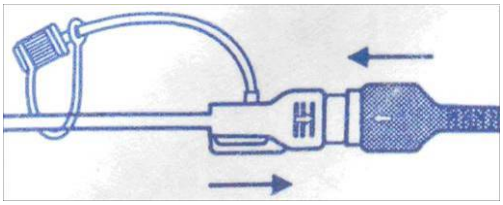


Figure 7-7 Connect catheter to pressure cable

3) Connect the IUP cable to the connecting cable. (They might have already been well connected in the package.)
4) Plug the connecting cable to the TOCO/IUP socket of the monitor.
5) Momentarily pressing the re-zero button on the IUP cable. The green light on the cable will flash for five seconds. During this time, zero the monitor by pressing the **AUTO ZERO** key. Make sure the display value and trend are both "0".
6) Ask the mother to cough. A spike on the trend in response to the cough indicates proper positioning and function of the IUPC.
7) Wash timely during monitoring. A spike on the tracing will respond to the washing.

7.6.4 Checking Intrauterine Pressure Cable Function

To test an IUP cable's function:

1) Disconnect the catheter from the cable. Insert the cable check plug into the catheter end of the cable. (See Figure 7-8).

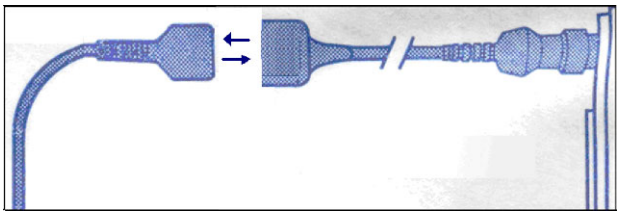


Figure 7-8 Test the Pressure Cable

2) Verify that the green light is continuously lit (no flashing).
3) If the light does not illuminate, replace the cable.

NOTE:

If the light is flashing, verify that the cable check plug is inserted completely into the cable.

⚠WARNING⚠:

The cable test function is not meant to check the accuracy of the system, only to confirm cable function.

7.7 Fetal Movement Monitoring

The fetal movement count on the main interface comes either from ultrasound (AFM) or remote event marker (Manual).

7.7.1 Choosing the FM Source

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **FMSource**; press the **CHANNEL** key.
3 Press the **UP** key or **DOWN** key to toggle between **Manual** (default) and **AFM**.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.7.2 Auto Fetal Movement Monitoring (AFM)

During fetal heart monitoring with ultrasound, the fetal movement signals are also detected. The fetal movement signals differ from the Doppler heart rate signals in that they have larger extent and lower frequency. The larger extent is because of the bigger scope of moving areas (e.g., the

fetal arms or legs); lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart.

Only FHR1 channel can perform AFM. But be aware that when monitoring twins, the movements detected by FHR1 may also be caused by the second fetus's movement.

The movement of the fetus will be detected and displayed in the form of a trend on the screen and the recorder paper.

You can choose whether to display the AFM trend and change the AFM threshold & AFM gain.

7.7.3 Enabling/Disabling AFM Trend

To enable or disable the AFM trend,

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.

2 Press the **UP** key or **DOWN** key to move the cursor to **AFM Enabled**; press the **CHANNEL** key.

3 Press the **UP** key or **DOWN** key to toggle between **On** (default) and **Off**.

4 Press the **CHANNEL** key to confirm selection.

5 Press the **AUTO** key to exit.

7.7.4 Changing AFM Threshold

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.

2 Press the **UP** key or **DOWN** key to move the cursor to **AFMThreshold**; press the **CHANNEL** key.

3 Press the **UP** key or **DOWN** key to choose the threshold from 0 ~100, the default value is **30**.

4 Press the **CHANNEL** key to confirm selection.

5 Press the **AUTO** key to exit.

7.7.5 Changing AFM Gain

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.

2 Press the **UP** key or **DOWN** key to move the cursor to **AFMGain**; press the **CHANNEL** key.

3 Press the **UP** key or **DOWN** key to choose the gain from 1, 2, 3 and 4 (default).

4 Press the **CHANNEL** key to confirm selection.

5 Press the **AUTO** key to exit.

7.7.6 Manual Fetal Movement Monitoring (MFM)

MFM result comes from the patient's feeling of fetal movement. The MFM symbol "↑" will be printed on the recorder paper.

1) Insert the remote event marker connector into the **MARK** socket on the monitor.

2) Let the patient hold the marker in hand; ask her to press the top key of it when a fetal movement is felt. Continuous movements in 5 seconds are considered to be one movement and only press the key once.

7.7.7 Clearing FM Count

When you want to clear the FM count, you can either press the **AUTO** key to start a new monitoring, or

1 Press the **SETUP** key once to open the **Function** menu.
2 Press the **UP** key or **DOWN** key to move the cursor to **ClearFM**.
3 Press the **CHANNEL** key to confirm selection.
4 Press the **AUTO** key to exit.

7.8 Login

7.8.1Inputting Patient's Bed ID

The bed ID you input for the patient will be printed on the recorder paper.

1 Press the **SETUP** key three times to open the **Fetal Monitor Configuration** menu.
2 Press the **CHANNEL** key when the cursor stays at **BedID**.
3 Press the **UP** key or **DOWN** key to choose the bed ID from 1 ~ 99.
4 Press the **CHANNEL** key to confirm selection.
5 Press the **AUTO** key to exit.

7.8.2 Inputting Patient's Information

It's recommended to input the patient's information. This information will appear beneath the loaded trends.

1 Press the **SETUP** key once to open the **Function** menu.
2 Press the **CHANNEL** key when the cursor stays at **Login**.
3 An ID that is composed of time or the previous ID appears in the ID area. Press the **CHANNEL** key, the cursor moves to the symbols area below. Press the **UP** key or **DOWN** key to move the cursor left or right. Press the **FREEZE** key to move the cursor up and down. Press the **CHANNEL** key at the <- symbol to delete an inputted symbol. Press the **CHANNEL** key at the OK symbol to finish inputting. You can input 10 characters at most.
4 Press the **UP** key or **DOWN** key to move the cursor to **NAME**, press the **CHANNEL** key. Input the patient's name in the same way. You can input 10 characters at most.

5 Press the **UP** key or **DOWN** key to move the cursor to **GesWeek**, press the **CHANNEL** key. Input the patient's name in the same way. Press the **CHANNEL** to confirm selection.

6 Press the **UP** key or **DOWN** key to move the cursor to **GesDay**, press the **CHANNEL** key. Input the patient's name in the same way. Press the **CHANNEL** to confirm selection.

7 Press the **AUTO** key to exit.

7.8.3 Enabling / Disabling Manual Login

If the manual login is enabled, the login menu pops up when you press the **AUTO** key to start monitoring. To enable or disable the manual login,

1 Press the **SETUP** key six times to open the **Auto Monitor** menu.

2 Press the **UP** key or **DOWN** key to move the cursor to **Login**; press the **CHANNEL** key.

3 Press the **UP** key or **DOWN** key to toggle between **ON** and **OFF** (default).

4 Press the **CHANNEL** key to confirm selection.

5 Press the **AUTO** key to exit.

The monitoring starts immediately after exiting from the menu.

7.9 Start Monitoring

After the **AUTO** key is pressed, the monitor automatically zeroes the TOCO value, clears FM count, adjusts fetal heart audio volume to default level, zeroes the monitoring time length and starts monitoring.

If the Auto-print is switched off, press the **PRINT** key to start printing.

7.10 Screen Display

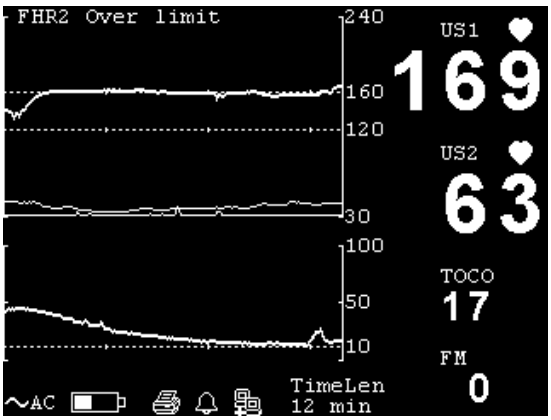


Figure 7-9 Fetal monitoring screen display

7.10.1 Fetal Monitoring Trends

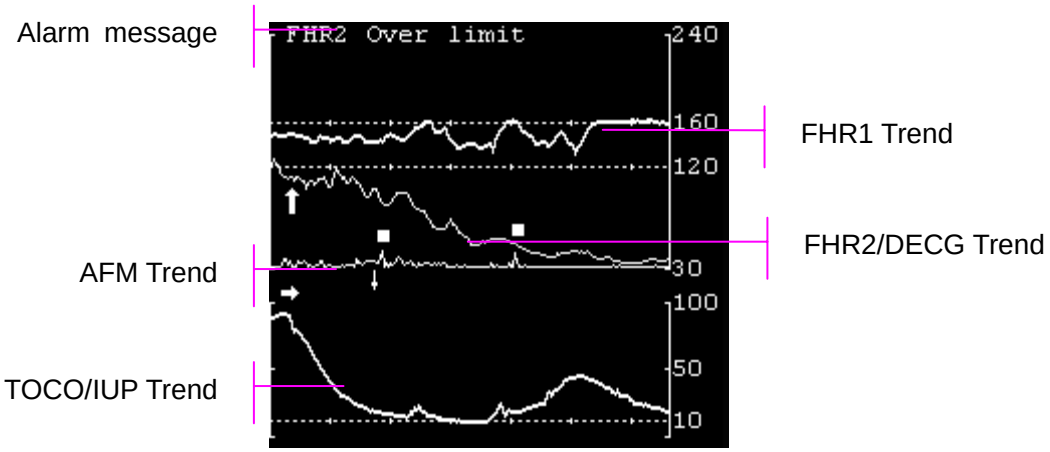


Figure 7-10 Fetal monitoring trends

During monitoring or playback, the trend frame displays four trends at most (refer to Figure 7-10): FHR1 trend, FHR2/DECG trend, AFM trend and TOCO/IUP trend.

FHR1, FHR2/DECG trend

FHR1 trend is the broad one.

The y-axis of the trend indicates the values of FHR, whose range is 30 ~ 240bpm (American standard) or 50 ~ 210bmp (International standard).

AFM trend

The y-axis indicates the scope of fetal movement.

NOTE:

The AFM trend is only for reference, please take the MFM marks as criterion.

TOCO/IUP trend

The y-axis indicates the value of TOCO/IUP, whose range is 0% ~ 100%.

7.10.2 Trends Playback

The monitor stores data of the latest 12 hours in its long-term memory. Playback allows you to review them.

Press the **FREEZE** key on the main interface, a playback symbol <--> appears in the trend area. Now you can press the **DOWN** key to play the trends backward. The symbol turns into <. Keep pressing it to accelerate until it reaches the maximum speed; the symbol turns into <<<<<. Press the **UP** key to decelerate.

In this process, press the **FREEZE** key to pause. The symbol turns into <--> again. If the **PRINT** key is pressed at this moment, the recorder will print the trends of 20 minutes (at most) starting from the left edge of the screen.

Press the **UP** key to play the trends forward. The symbol turns into >. Keep pressing it to accelerate until it reaches the maximum speed; the symbol turns into >>>>>. Press the **DOWN** key to decelerate.

During playback, the current patient monitoring does not stop. The fetal heart sound and FHR values are all real-time information of the patient.

During playback pause, press the **FREEZE** key to return to real-time monitoring.

⚠CAUTION⚠:

Playback must pause before printing starts. Printing in the process of playback might result in failure information on the paper.

NOTE:

The process of playback does not bear the limit of returning to the upper directory interface if no operation is performed within 30 seconds.

7.10.3 Trends Loading

When the 12-hour data stored in the monitor is loaded, the trends occupy the whole screen, and the patient's information appears beneath them.

To load the trends,

1 Press the **SETUP** key once to open the **Function** menu.
2 Press the **UP** key or the **DOWN** key to move the cursor to **Load**.
3 Press the **CHANNEL** key to confirm selection.

Review them in the same way as playback. The information of the patient will be updated synchronously.

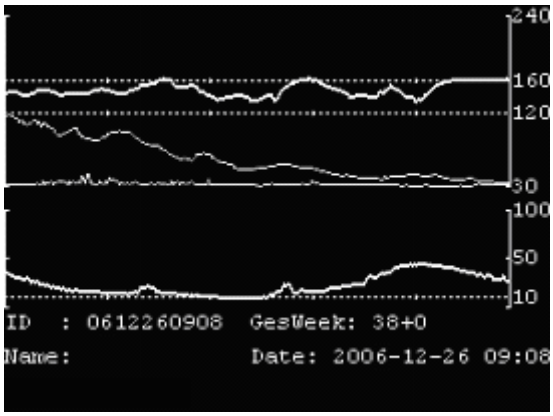


Figure 7-11 An example of loaded trends

7.10.4 Fetal Monitoring Values

	US1: FHR1 socket is connected with a US transducer. When nothing is connected, it displays **Off**.
	♥: FH refreshing rate
	169: FHR1 value.
	US2: FHR2 socket is connected with a US transducer. When DECG cable is connected to the DECG socket, it displays **DECG**. When nothing is connected, it displays **Off**.
	63: FHR2/DECG value.
	TOCO: The TOCO/IUP socket is connected with a TOCO transducer or DECG connecting cable. When nothing is connected, it displays **Off**.
	17: current UA value.
	FM: The FM count comes from the MFM. When the FM source is set to AFM, it displays **AFM**.
	1: FM count

7.11 Completing Monitoring

After monitoring,

1) Press the **PRINT** key to stop printing.
2) Remove transducers or electrodes from the patient; wipe the remaining gel off the patient and the US transducer with a clean soft cloth or tissue.
3) Tear off the printed recorder paper along the perforation.

7.12 Switching Off the Monitor

1) Press the **POWER** switch and hold for about 5 seconds.
2) Unplug the monitor.

⚠CAUTION⚠:

Do not press the POWER switch continuously. Allow at least 10 seconds between switching the monitor on and off.

Chapter 8 Maintenance, Care and Cleaning

8.1 Preventive Maintenance

8.1.1 Maintaining Inspection

(1) Visual Inspection

Prior to using the monitor every time, do the following inspections:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.

If any damage is detected, stop using the monitor on the patient. Replace the damage part(s) or contact EDAN for service before reusing it.

(2) Routine Inspection

The overall check of the monitor, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

1) Make sure all exposed screws are tight.
2) Check the external cables for splits, cracks or signs of twisting. Replace any cable that shows serious damage.
3) Pay particular attention to the supply socket.

⚠WARNING⚠:

Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

8.1.2 Maintenance of the Monitor

Keep the exterior surface of the monitor clean, free of dust and dirt.

The gathering of dew on the display may occur with abrupt temperature or humidity changes. A table environment is recommended.

Scratching and damaging the display should be avoided.

Avoid high voltage and static charge.

8.1.3 Maintenance of the Transducers

Keep the transducers in a dry environment, where the temperature does not exceed 45°C (113 ºF).

Gel must be wiped from the US transducer after use. These precautions will prolong the life of the transducer.

Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical parts. Contacting the transducers with hard or sharp objects should be avoided.

Do not excessively flex the cables.

8.1.4 Storage of Recorder Papers

When storing recorder papers (including used paper with trends):

Do not store them in plastic envelopes.

Do not expose them to direct sunlight or ultraviolet light.

Do not exceed a storage temperature of 40 ºC (104 ºF). Do not exceed a relative humidity of 80%. Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trend unreadable.

8.1.5 Cleaning of the Recorder

The recorder platen, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when the printed trends become faint).

To clean the recorder:

1) Clean the recorder platen with a lint-free cloth dampened in soap / water solution.

2) Wipe the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.

3) Check that the paper sensing mechanism is free of dust.

CAUTION:

Only use the recorder paper provided by EDAN, or it may damage the recorder. This kind of damage is not covered by warranty.

8.2 Cleaning

In order to avoid infection, clean and disinfect the monitor and accessories after each use.

8.2.1 Cleaning of the Monitor

⚠WARNING⚠:

Unplug the monitor from the AC power source and detach all accessories before cleaning.

Clean the monitor enclosure with a soft cloth and diluent non-caustic detergents, such as soft soap water, Tensides, Ethylate and Acetaldehyde.

Clean the screen with a dry soft cloth.

CAUTION:

1) Although the monitor is chemically resistant to most common hospital cleaners and non-caustic detergents, other cleaners are not recommended and may stain the monitor.
2) Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.
3) Don't use strong or chemical solvents, such as acetone, acidic or alkali solutions.
4) Never use an abrasive such as steel wool or metal polish.
5) Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.
6) Avoid pouring liquids on the monitor while cleaning.
7) Do not remain any cleaning solution on the surface of the monitor.

NOTES:

1) The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
2) EDAN has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

8.2.2 Cleaning of the Accessories

⚠WARNING⚠:

Detach the accessory from the monitor before cleaning.

(1) Cleaning of Transducers and Leads

To clean the US transducer, TOCO transducer, IUP cables, and DECG lead, follow these steps:

1) Wipe them with a soft cloth dampened in cleaning solution;
2) Clean them with a soft cloth dampened in water;
3) Air-dry them or wipe off the remaining moisture with a soft dry cloth.

The recommended cleansers for accessories are listed below:

Accessory	Cleansers
Ultrasound Transducer TOCO Transducer	BURATON LIQUID MIKROZID ETHANOL 70% SPORACIDIN CIDEX
DECG Leads, IUP cable, IUP connecting cable	Mild alcohol-free soap water

CAUTION:

1) Be sure the temperature of cleaning solutions does not exceed 45 ºC (113 ºF).
2) Do not immerse them in any liquid.
3) Only clean the outer surface of the connectors, make sure no liquid goes into the connector.
4) After cleaning, no remaining cleanser is allowed on the surface.

(2) Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed 60 ºC (140 ºF).

8.3 Disinfecting

Clean the equipment before disinfecting.

The table below lists the allowed disinfectant bases:

Type	Base
Instrument Disinfectant	Glutaraldehyde up to 3.6%
Surface Disinfectant	Ethanol 1- and 2- Propanol

CAUTION:

1) Do not use any disinfectant containing additional active ingredients other than those listed.

2) Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.
3) Do not immerse any part of the monitor or any accessory into liquid.
4) After disinfection, no remaining disinfectant is allowed on the surface.
5) Check if the monitor and accessories are in good condition. If any aging or damage is detected, replace the damage part(s) or contact EDAN for service before reusing them.

NOTE:

EDAN has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

8.4 Sterilizing

Do not sterilize the monitor or the accessories, unless this is necessary according to your hospital regulation.

Chapter 9 Warranty and After-Sales Service

9.1 Warranty

EDAN’s obligation under this warranty is limited to repairing, at EDAN’s option, any part which upon EDAN's examination proves defective. If the product doesn’t function as warranted during the warranty period, we will repair or replace it without charge.

Material and Manufacture

EDAN warrant that there’s no defect in material and manufacture. During the warranty period, EDAN will repair or replace the defective part free if the defect has been confirmed as material or manufacture defect.

Software or Firmware

EDAN software and firmware products which are designated by EDAN for use with a hardware product, when properly installed on that hardware product, are warranted not to fail to execute their programming instructions due to defects in materials and workmanship. If EDAN receives notice of such defects during the warranty period that begins on the date of shipment, EDAN shall repair or replace software media or firmware which does not execute their programming instructions due to such defects. But EDAN doesn’t warrant that operating of the hardware, software, or firmware shall be uninterrupted or free from error.

NOTE: The charges of freight and others are excluded under warranty.

This unit has no parts can be repaired by users themselves. All the service should be performed by authorized and qualified personnel.

Limit of Warranty

The warranty is void in the case of

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized persons;
- Subsequent damage caused by improper use or maintenance;
- Replacement or remove of Serial number label and manufacturer label;

9.2 After-Sales Service

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Product Specifications

A1.1 Environmental Specifications

Working	Temperature:	+5 ºC ~+ 40 ºC (+41 ºF ~ +104 ºF)
	Relative Humidity:	25% ~ 80% (non-condensing)
	Atmospheric Pressure:	860hPa ~ 1060hPa
Transport and Storage	Temperature:	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)
	Relative Humidity:	25% ~ 93% (non-condensing)
	Atmospheric Pressure:	700hPa ~ 1060hPa

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size mm (depth x width x height) :	330mm x 270mm x 100mm
	Weight:	Approx. 3.6 kg
Power Supply	Operating Voltage:	100V-240V~
	Operating Frequency:	50Hz/60Hz
	Input Power :	60VA
	Battery:	14.8V/6600mAh
Standards Compliance	IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 61157, IEC/EN 60601-2-37, IEC/EN 60601-1-2:2001+A1	

Anti-electric Shock Type	Class I equipment with internal power supply
Anti-electric Shock Degree	FHR1, FHR2, TOCO, FM, FS B IUP BF DECG CF
Degree of Protection against Harmful Ingress of Water	Ordinary equipment (sealed equipment without liquid proof)
Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
Disinfection/Sterilizing Method	Refer to this user manual for details
EMC	Group I Class A

Working System		Continuous running equipment
Earth Leakage Current (Limit)		N.C. S.F.C. 500μA 1000μA
Enclosure Leakage Current (Limit)		N.C. S.F.C. 100μA 500μA
Patient Leakage Current (Limit)		N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Patient Auxiliary Current (Limit)		N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Display	LCD Size	5.7”
	Active Area:	103.0(W) x 79.0(H) mm (320 x 240 dots)
	Resolution:	85 dots per inch
	Backlight:	Cold cathode fluorescent
Signal Interface	DB9 network interface	

Ultrasound Transducer	
Weight:	190g
Cable Length:	2.5m
Dimension:	88mm×35mm
TOCO Transducer	
Weight:	180g
Cable Length:	2.5m
Dimension:	88mm×35mm
Remote Event Marker	
Length:	2.5m
Weight:	56g

A1.3 Performance Specifications

Ultrasound	Technique:	Ultrasound Pulse Doppler with autocorrelation
	Pulse Repetition Rate:	2 KHz
	Pulse Duration:	92 μs
	Ultrasound Frequency:	(1.0±10%) MHz

	p- <1 MPa	
	I_{ob} <10 mW/cm^2	
	I_{spta} <100 mW/cm^2	
	FHR Measurement Range:	50 bpm ~ 240 bpm
	Resolution:	1 bpm
	Accuracy:	±2 bpm
	Dielectric Strength:	> 4000Vrms
	ISATA@ the transducer face: 1.865 mW/cm^2	
	Entrance beam: 6.08 cm^2	
	Measurement uncertainties for ISATA: ±26.6%	
	Measurement uncertainties for ultrasonic power: ±26.6%	
DECG	Technique:	Peak-peak detection technique
	DFHR Measurement Range:	30bpm ~ 240bpm
	Resolution:	1bpm
	Accuracy:	±1bpm
	Input Impedance:	> 10M (Differential, DC50/60Hz)
	Input Impedance:	> 20M (Common Mode)
	CMRR:	> 110dB
	Noise:	< 4μVp
	Skin Voltage Tolerance:	±500mV
	Fetal Input Voltage Current:	20μVp ~ 3mVp
TOCO	TOCO Range:	0% ~ 100%,
	Non-linear Error:	10%
	Resolution:	1%
	Zero Mode:	Automatic/ Manual
	Dielectric Strength:	> 4000Vrms
IUP	Pressure Range:	0 mmHg ~ 100 mmHg
	Sensitivity:	5μV/V/mmHg
	Non-linear Error:	± 3mmHg
	Resolution:	1%
	Zero Mode:	Automatic / Manual

AFM	Technique:	Pulsed Doppler ultrasound
	Range:	0% ~ 100%,
	Resolution:	1%
Marking	Manual fetal movement mark	

A1.4 Recorder Specifications

Recorder paper:	Z-fold, thermal
Printing Width:	112mm
Effective Printing Width:	104mm
Paper Advance Speed:	1cm/min, 2cm/min and 3cm/min optional
FHR/DECG Printout Width:	7cm (USA standard) / 8cm (international standard)
FHR/DECG Scaling:	30bpm/cm (USA standard) / 20bpm/cm (international standard)
TOCO/IUP Printout Width:	3.4cm (USA standard) / 2.4cm (international standard)
TOCO/IUP Scaling:	25%/0.85cm (USA standard) / 25%/0.6cm (international standard)
Data Accuracy:	±5% (X axis), ±1% (Y axis)
Record Message:	Date, time, TOCO type, paper speed, FHR type, bed No., etc.

A1.5 Lithium-ion Battery Specifications

Operating Temperature	-20°C to 35°C (-4°F to 95°F)
Relative Humidity	65±20%
Nominal Capacity	6600mAh
Continuous Working Time	4 hours
Necessary Charge time	6 hours
Nominal Voltage	14.8V
Charge Mode	Constant current/ constant voltage
Charge Current (Standard)	$0.2C_5A$(1200mA)
Charge Voltage (Standard)	(16.8±0.1) V

The Maximum Charge Current Continuously	2000mA
Storage	Short Term (within 1 month): -20 ºC to 60 ºC (-4 ºF to 140 ºF) Middle Term (within 3 months): -20 ºC to 45 ºC (-4 ºF to 113 ºF) Long Term (within 1 year): -20 ºC to 20 ºC (-4 ºF to 68 ºF) During storage, recharge the battery at least every six months.
Charge State When Leaving Factory	20% ~ 50%
Cycle Life	≥500 times

A1.6 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

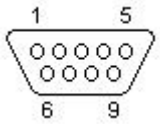
System: CADENCE series Fetal Monitor

Transducer Model	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$Ipa.3@MI_{max}$ (W/cm^2)
PW 1.0 MHz	2.77	TIS	0.055	0.029	0.01
		TIB	0.629		

Appendix 2 Signal Input/Output Connector

Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, contact our technical service department or your local distributor.

DB9 Interface



Pin	Signal	Input/Output
1	+5V	Output
2	Rx	Input
3	Tx	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input

Appendix 3 Troubleshooting

A3.1 No Display

Symptom	Possible Cause	Solution
Power indicator is off	Power cable is loose and no battery	Tighten the power cable and check the fuse, or check the battery
	The fuse(s) is (are) blown.	Replace the fuse(s).
	The battery is low.	Connect the monitor to AC power.

A3.2 Noise

Symptom	Possible Cause	Solution
Noise	The FHR volume is set to be too high.	Adjust the volume down
	Interfered by handset or other interfering source	Keep the handset or other interfering source far away

A3.3 Recorder Error

Symptom	Possible Cause	Solution
Paper jam	Wrong feeding paper or paper is affected by damp.	Feed paper correctly and keep paper from moist
Recorder does not work	The **PRINT** key is disabled	Press the **PRINT** key again
	Out of paper	Feed paper
	Ultrasound transducer or DECG cable connector is unplugged.	Connect with ultrasound transducer or DECG cable connector

A3.4 Ultrasound Monitoring of FHR

Phenomenon	Possible Cause	Solution
Inconstant trace / display	Thick abdominal wall	Monitor FHR with DECG if the membrane is adequately ruptured.
	Improper ultrasound transducer position.	Adjust the position of the transducer till the better signal is received.
	Loose belt.	Tighten the belt.
	Superfluous aquasonic coupling gel.	Wipe off superfluous aquasonic coupling gel.
	Frequent fetal movements.	Delay the monitoring.
	Maternal movement.	Request the patient to calm down and stay still.
	Inadequate aquasonic coupling gel.	Use recommended aquasonic coupling gel quantity.
Doubtful FHR	Record maternal heart rate wrongly.	Change the position of the ultrasound transducer.
	The transducer is not well placed in position, and the mixed noise has been recorded.	Adjust the position of the transducer.
Faint trace or no trace	Improper paper	Use the paper recommended by the manufacturer.
	Adjusting nuts of the print head are unbalanced.	Contact EDAN for service.

A3.5 DECG Monitoring of FHR

Symptom	Possible Cause	Solution
Inconstant trend Inconstant display	No ECG signal	Use a new spiral electrode
	Bad contact of reference electrode and patient	Use a new spiral electrode
Inconstant trend	The DECG cable has not been fixed firmly	Fix an attachment pad at the DECG cable.

A3.6 Monitoring Contractions (External)

Symptom	Possible Cause	Solution
Poor trend quality or fluctuant UA baseline	The belt is too tight, too loose or has no elasticity.	Ensure the belt has been used accurately and neither too tight, nor too loose.
	Maternal movement	Relax the patient.
	Fetal movement	Wait for a moment.
Too high TOCO sensitivity (higher than 100 unit)	The uterus pressure is far higher than the average value.	Make sure the TOCO transducer is well contacted with the abdominal skin. Reposition of TOCO transducer if necessary.

A3.7 Monitoring Contractions (Internal)

Symptom	Possible Cause	Solution
No trend	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	“Dry” environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system
The trend is in a beeline.	The connector failure.	Move or reposition the catheter. If the trend still displays no fluctuation, change intrauterine cable.

A3.8 Blown Fuses

⚠WARNING⚠:

Switch off the monitor and unplug it before changing the fuse.

Replace the fuse when it is blown.

The two fuses of CADENCE II monitor are located on the right panel, their specifications are:

Size: Φ5mm*20mm; Model: T1.6AL 250V.

To replace a fuse:

- Place the monitor on a flat surface.
- With a flat-head screw driver, push the fuse in for about 1 mm and then unscrew it anticlockwise.
- Remove the old fuse and replace it with a new fuse that is supplied by EDAN or of the same specifications.
- Push the new fuse into the socket for about 1 mm and then screw it clockwise back in position.

Appendix 4 EMC Information – Guidance and Manufacture's Declaration

A4.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *CADENCE II Fetal Monitor* is intended for use in the electromagnetic environment specified below. The customer of the user of the *CADENCE II Fetal Monitor* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *CADENCE II Fetal Monitor* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The *CADENCE II Fetal Monitor* is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A4.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *CADENCE II Fetal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of CADENCE II Fetal Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz, 60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *CADENCE II Fetal Monitor* requires continued operation during power mains interruptions, it is recommended that the *CADENCE II Fetal Monitor* be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

A4.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The CADENCE II Fetal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of CADENCE II Fetal Monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>$3V_{rms}$

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the CADENCE II Fetal Monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CADENCE II Fetal Monitor is used exceeds the applicable RF compliance level above, the *CADENCE II Fetal Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *CADENCE II Fetal Monitor*.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A4.4 Recommended Separation Distance

Recommended separation distances between portable and mobile RF communications equipment and the *CADENCE II Fetal Monitor*

The *CADENCE II Fetal Monitor* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *CADENCE II Fetal Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *CADENCE II Fetal Monitor* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EDAN INSTRUMENTS, INC.
3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou,
Nanshan Shenzhen, 518067 P.R. CHINA
TEL: +86-755-26882220 FAX: +86-755-26882223

EC REPRESENTATIVE
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg Germany
TEL: +49-40-2513175 FAX: +49-40-255726
E-mail: antonjin@yahoo.com.cn